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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,357	09/24/2001	Nicholas F. D'Antonio	DA7119US (#90036)	7922

28672 7590 08/09/2005

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,357

Applicant(s)

D'ANTONIO ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 36-48, 50, 51, 59, 62, 64-67 and 69-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-10, 12-15, 18, 19, 21, 23-35, 49, 52-55, 57, 58, 60, 61, 63, 68 and 88-91 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1,2,5-10,12-15,18,19,21,23-35,49,52-55,57,58,60,61,63,68 and 88-91.

DETAILED ACTION

Election/Restrictions

Applicant's election of group I (claims 1, 2, 5-10, 12-15, 18, 19, 21, 23-35, 49, 52-55, 57, 58, 60, 61, 63, 68, and new claims 88-91) in the reply filed on May 16, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 36-48, 50-51, 59, 62, 64-67 and 69-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention,. Election was made **without** traverse in the reply filed on April 29, 2004.

(Claims 3, 4, 11, 16, 17, 20, 22, 56 have been cancelled).

Claim Objections

Claims 31 is objected to because of the following informalities:

in claim 31, line 2, before "a drive", there should be –further comprising;

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1641

Claims 24, 25, 51 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24, line 2, recites the limitation "said housing". It is unclear as to which housing since Applicant recites two different housings in the claim.

Claim 25, line 2, recites the limitation orifices. There is insufficient antecedent basis for this limitation in the claim.

Claim 51, last line, recites the limitation "cartridges". There is insufficient antecedent basis for this limitation in the claim (it should be "container(s)").

Claim 63, line 5, recites the limitation "for the non-physical contact release". It is unclear as to the non-physical contact of or by what. (It appears that Applicant intended to refer to the non-physical contact by a user.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1641

1. Claims 1,2, 5-10, 12-15, 18, 19, 21, 23-35, 49, 53-55, 57, 58, 60, 61, 63, 68, 88-91 are rejected under 35 U.S.C. 102(e) as being anticipated by D'Antonio et al., 6,056,716.

As to claims 1,2, 5, 12, 13, 15, 23, 27, 29, 31, 49, 53, 54, 60, 61, 63, D'Antonio discloses a housing (proximal portion of 707, fig. 7E) for housing at least two injectate cartridges (or containers) (845) each of said cartridges having a dispensing channel with an exit nozzle (842', col. 26, lines 52-54), and a plunger (847, col. 26, line 59) for moving through each of the cartridges to dispense injectate from the cartridges;

a holding member (840) for holding the respective injectate cartridges with said dispensing channels directed in a common direction;

a latching and release apparatus (708, see fig. 7E) included in or on said housing for latching said holding member to said housing and for releasing said holding member and the injectate cartridges held thereby for non-contaminating disposal after the injection process (additionally, the container is spaced away from the housing (see 101 in fig. 7E);

a ram apparatus (848) having separate rams (848), each movable with respect to one of said cartridges to move the respective plungers simultaneously for forcing injectate simultaneously from said cartridges through the dispensing channels and the individual exit nozzle (col. 60-63);

a carriage (849) movable from a set position to a dispensing position for moving said ram apparatus at uniform pressures during an injection process

Art Unit: 1641

a spring apparatus (227, or see column 26, lines 61-64) for moving said carriage from the set position to the dispensing position (for **claims 7-9, 18**, also);

a carriage resetting apparatus (436) for moving said carriage from the dispensing position to the set position and for recocking said spring apparatus, (see column 10, line 46 – column 11, line 20),

and a releasable latching device for latching said spring apparatus is disclosed, (see column 11, lines 14-20) (for **claim 10** also),

said latching and release apparatus (708) supports said holding member spacing the front end of said holding member away from said housing (see figure 7E for assembly) to avoid contact of said housing with any contaminant on the front end of said holding member or the cartridges. (Although holding member 708 is not entirely spaced away from the housing, at least the front end of the holding member is spaced away from the housing.)

As to claim 6, said release apparatus includes a groove (see front end of 820 in figure 7E, or front end of 836 in figure 7F) in the front plate and a releasable latching member (714, see figure 7E) in the housing.

As to claim 7, a manually operable trigger device (701) is disclosed; wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

As to claims 8-9, a trigger (701) holding a spring/energy storing apparatus (227) in a set condition is disclosed in fig. 2AA and 7A.)

Art Unit: 1641

As to claim 10, the locking and release apparatus (708, see fig. 7E) comprises a locking member (712) considered to be cooperating with container-holding member to lock said holding member to said housing, and a releasing apparatus (708) for releasing the locking member and an ejection device for ejecting the container-holding member.

As to claim 14, one of the cartridges are considered inactive, since this is an intended use and the cartridge is capable of being inactive.

As to claim 18, a biasing device (848) for placing pressure on the containers to force the injectate out of the containers at jet velocity is disclosed, (see fig. 7GG).

As to claims 19 and 55, there are six cartridges, see figure 7GG.

As to claim 21, holding member has at least two openings (proximal and distal openings (fig 7GG.)

As to claims 24 and 65, the device further includes a jet injector housing (distal portion of 707) wherein said housing is for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said latching device, said carriage resetting apparatus and said releasable latching device.

As to claims 25, 89, 90, since it is not clear as to what orifice Applicant is referring, Examiner considers the orifice to be at (842') and the guard plate (or guard wall as to claim 89) is at distal end of (840.)

As to claims 26 and 32, a cam and cam follower as claimed is disclosed, see column 10, lines 46-59.

As to claim 28, a spring apparatus with movable rods (227 or see column 26, lines 61-64) for moving said carriage as claimed is disclosed.

Art Unit: 1641

As to claim 30, a solenoid as claimed is disclosed at (48).

As to claims 31 and 33, a drive apparatus moved by a motor driven device (221) is disclosed, see column 9, line 63 – column 10, line 17.

As to claims 34, 88, 91, a loading station with a motor to operate said carriage resetting apparatus is disclosed, see column 10, lines 10-17.

As to claim 35, a sensing apparatus as claimed is disclosed in column 24, lines 24-27.

As to claims 57, the pattern of the holding member is a circle, and there are five exit nozzles equally disposed around the perimeter of the circle, and one exit nozzle disposed at the center of the circle (figure 7GG.

As to claim 58, the pattern of the holding member is a circle, and there are six exit nozzles as claimed (see figure 7GG.)

As to claim 68, the latch and release apparatus (708) is manually actuable.

2. As to claims 1,2, 5-10, 12-15, 18, 19, 21, 49, 52-55, 60-63, 68, 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Tarello et al., 4,518,384.

As to claims 1,2, 5, 12, 13, 15, 49, 53, 54 and 60-63, Tarello et al. discloses a housing (56 and 60) for housing at least two injectate cartridges (or containers) (18) each of said cartridges having a dispensing channel with an exit nozzle (near 28), and a

Art Unit: 1641

plunger (30) for moving through each of the cartridges to dispense injectate from the cartridges;

a holding member (14) for holding the respective injectate cartridges with said dispensing channels directed in a common direction;

a latching and release apparatus (54 and 64, see col. 5, line 14 and fig. 1) included in or on said housing for latching said holding member to said housing and for releasing said holding member and the injectate cartridges held thereby for non-contaminating disposal after the injection process;

and a releasable latching device (54 and 64) for latching said spring apparatus is disclosed,

said latching and release apparatus (54 and 64) supports said holding member spacing the front end of said holding member away from said housing (see figure 2) to avoid contact of said housing with any contaminant on the front end of said holding member or the cartridges. (The front end of the holding member is spaced away from the housing.)

As to claim 6, said release apparatus includes a groove (64) in the front plate and a releasable latching member (see fig. 1) in the housing.

As to claim 7, a manually operable trigger device (12) is disclosed; wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

Art Unit: 1641

As to claims 8-9, a trigger (12) holding a spring/energy storing apparatus (68) in a set condition is disclosed, (see fig. 2.)

As to claim 10, the locking and release apparatus (34, 54 and 64) comprises a locking member (64, see fig. 1) cooperating with container-holding member to lock said holding member to said housing, and a releasing apparatus (34) for releasing the locking member and an ejection device for ejecting the container-holding member.

As to claim 14, one of the cartridges are considered inactive, since this is an intended use and the cartridge is capable of being inactive.

As to claim 18, a biasing device 68() for placing pressure on the containers to force the injectate out of the containers at jet velocity is disclosed, (see fig. 2)

As to claims 19 and 55, there are six cartridges, see figure 2. (The Office notes that the claims do not require that there be only six cartridges.)

As to claim 21, holding member has at least two openings (proximal and distal end of 14, see fig. 2.)

As to claim 90, since it is not clear as to what orifice Applicant is referring, Examiner considers the orifice to be (near 28, see fig. 3).

As to claim 68, the latch and release apparatus (54 and 64) is manually actuable.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1641

Applicant's amendment has overcome the rejections in the previous Office action. The previous Office action relied on the embodiment of the D'Antonio invention as shown in figure 7A. However, based on the new limitations, Examiner is relying on a different embodiment (embodiment in figure 7GG) in the D'Antonio reference in rejecting the new amendments.

With regards to the new limitations, as indicated above, although holding member (708) is not entirely spaced away from the housing, at least the front end of the holding member is spaced away from the housing. The cartridges are also spaced away from the housing, see 7GG, and 7E for the assembly.)

With respect to claims 19 and 55-58, those claims were rejected under U.S.C. 103 in the previous Office action, which relied on embodiment in Figure 7A in D'Antonio in the rejection. However, because of the new limitations, the embodiment in Figure 7GG is relied on in the above rejection. According to the embodiment in Figure 7GG, claims 19 and 55-58 are rejected under U.S.C. 102 since the embodiment in Figure 7GG discloses every limitation claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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08/08/05